UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/303,040	04/30/1999	BARBARA J. WINSLOW	54957-B/JPW/	7815

27123 7590 01/05/2006

MORGAN & FINNEGAN, L.L.P.
3 WORLD FINANCIAL CENTER
NEW YORK, NY 10281-2101

EXAMINER	
WINKLER, ULRIKE	
ART UNIT	**PAPER NUMBER**
1648	

DATE MAILED: 01/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/303,040	WINSLOW ET AL.	
	Examiner	Art Unit	
	Ulrike Winkler	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 September 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *37-65 and 67-77* is/are pending in the application.

4a) Of the above claim(s) *38-40,42-47,49-53,55-57,60-65 and 67-75* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *37, 41, 48, 54, 58, 59, 76, 77* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's election with traverse of Group I, with further election of feline CD 86 protein and swinepox in the response of September 28, 2005 is acknowledged. The traversal is on the ground(s) that "a search of the prior art in 1 subclass within the same class cannot be deemed as "undue diverse searching."" Applicants question whether the separation between feline CD28 protein, feline CD86 protein, feline CD80 protein and feline CTLA-4 is a species restriction or whether the Office intended this to be a restriction into different groups. In order to qualify as a species and thus be treated as a Markush group (species) the molecules comprising the different species need to (1) share a common utility and (2) share a substantial structural feature disclosed as being essential to that utility. Applicants have not shown that feline CD28 protein, feline CD86 protein, feline CD80 protein and feline CTLA-4 share a substantial structural feature that is essential for their utility. Thus, feline CD28 protein, feline CD86 protein, feline CD80 protein and feline CTLA-4 cannot be considered species of each other and therefore the structures are properly placed into different groups. The structures are placed into different groups even though they are classified in the same class and subclass.

Racconpox virus, swinepox virus and feline herpes virus all are DNA viruses but there is no indication that these different viruses share a common structural feature that is disclosed as being essential for the utility of the viruses. Therefore, the viruses are properly grouped into separate groupings even though they are found in

the same subclass. The different viruses have different structures, modes of operation and different effects, thus they are distinct from each other.

A search for a viral vector that contains only one foreign nucleic acid will not be coextensive with a search for a viral vector that contains 4 foreign nucleic acid structures. Thus the different structures are properly grouped into different groups and are then linked by the generic claim.

Applicants' are always free to go on the record unequivocally stating that the structures placed into the different groups by the Office are not patentably distinct. Applicant should submit evidence or identify such evidence now of record showing the groups to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.§103(a) of the other invention.

The restriction requirement is still deemed proper and is therefore made FINAL.

Claims 37, 41, 48, 54, 56, 58, 59, 76 and 77 are under consideration in the instant Office actions as being drawn to the elected invention of group I, with further election of feline CD 86.

Specification

Applicant is required to update the status (pending, allowed, ect.) of all parent priority applications in the first line of the specification.

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

Sequence listing

Applicant's CRF and paper sequence listing have been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 37, 41, 48, 54, 56, 58, 59, 76 and 77 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are rendered indefinite in that they only describe the composition by an arbitrary name. While the name itself may have some notion of activity of the protein, there is nothing in the claims that distinctly describes the feline CD28 protein, feline CD80 protein, feline CD86 protein or feline CTLA-4 protein and variants thereof. For example, others in the field may isolate the same protein and give it an entirely different name. Applicant should particularly point out and distinctly claim the "protein molecule and variant thereof' by claiming characteristics associated with the protein (e.g. activity, molecular weight, amino acid composition, sequence identifier, N-terminal sequence, etc.). Claiming a biochemical molecule by a particular name given to the protein by the various workers in the field fails to distinctly claim what that protein is and what the composition is made of.

Claims 58 and 59 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant

regards as the invention. The claims make reference to a vaccine composition, it is not clear to what structure the immune response is to be directed. Is it the structure of the CD86 inserted into the recombinant virus or is the immunogenic reaction (vaccine) directed to the recombinant virus. It is not clear to the office how a composition eliciting an antibody response to CD86 will function as a vaccine. Vacccines by definition are prophylactic yet it is not clear to what stuctre the composition should elicit the prophylactic immune response.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 58 and 59 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for expressing CD86 using a vial vector, does not reasonably provide enablement for a vaccine. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. The term "vaccine" implies any preparation intended for active immunological prophylaxis; e.g., preparations of killed microbes of virulent strains or living microbes of attenuated (variant or mutant) strains; or microbial, fungal, plant, protozoal, or metazoan derivatives or products. Although just about any protein when inoculated can cause an immune reaction, the prophylactic nature of this reaction is not guaranteed and has to be experimentally determined. Prophylaxis is defined as the prevention of disease or of a process that can lead to disease. This is achieved by use of an antigenic (immunogenic) agent to actively stimulate the immunological mechanism, or the administration of chemicals or drugs to members

of a community to reduce the number of carriers of a disease and to prevent others contracting the disease. It is not clear if the protective immune response is directed to the recombinant virus or if it is directed to the CD86.

In this instance the recombinant virus can encompass a virus to which the animal is not known to elicit a protective immune response and could be fatal to the animal. There is no evidence that inserting CD86 into a virus that is ordinarily lethal to the animal will endow the virus with a protective response encompassed by the definition of a vaccine. In this instance the recombinant virus could be a feline immunodeficiency virus (FIV a lentivirus). FIV infection in cats is lethal, thus a recombinant FIV virus with CD86 inserted into the virus would not be expected to have prophylactic effect and thus would not qualify as a vaccine. However, the claims are broadly drawn to include such a structure. Even if the virus is ordinarily not lethal to the animal insertion of an additional component ordinarily expressed in the host animal can unpredictably transform the virus to become lethal in the animal (see Jackson et al. Journal of Virology. 2001). Thus is it not predicable if the insertion of CD86 into a virus will result in a composition that can be considered prophylactic to be considered a vaccine.

Applicant is reminded that any amendment must point to a basis in the specification so as not to add new matter. See MPEP 714.02 and 2163.06.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 37, 48, 56 and 58 are rejected under 35 U.S.C. 102(e) as being anticipated by Freeman et al. (U.S. Pat. No. 6,723,705; '705); or under 35 U.S.C. 102(a) and 35 U.S.C. 102(e) by Freeman et al. (U.S. Pat. No. 5,861,310; '310); or under 35 U.S.C. 102(b) Freeman et al. (WO 95/03408; WO).

The instant invention is drawn to a viral vector (recombinant virus) that contains at least one foreign nucleic acid inserted into the nucleic acid construct of the viral vector. The insertion site is within a non-essential region. The foreign protein comprises a feline CD86 protein or an immunogenic fragment thereof. The instant specification [paragraph 0056] indicates that the viral vector can contain DNA sequences that are functional conservative variants, and that can contain additional sequences.

> MPEP 2111.03 The transitional term "comprising", which is synonymous with "including," "containing," or "characterized by," is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See, e.g., *Genentech, Inc. v. Chiron Corp.*, 112 F.3d 495, 501, 42 USPQ2d 1608, 1613 (Fed. Cir. 1997) ("Comprising" is a term of art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within

the scope of the claim.); *Moleculon Research Corp. v. CBS*, Inc., 793 F.2d 1261, 229 USPQ 805 (Fed. Cir. 1986); *In re Baxter*, 656 F.2d 679, 686, 210 USPQ 795, 803 (CCPA 1981); *Ex parte Davis*, 80 USPQ 448, 450 (Bd. App. 1948) ("comprising" leaves "the claim open for the inclusion of unspecified ingredients even in major amounts").

The smallest peptide fragment (epitope) that can elicit an immune response is in an animal is a six amino acid stretch. If the prior art comprises stretches of six amino acids that are identical or "functional conservative variants" of the instantly claimed CD86 immunogenic fragments then the art meets the limitation of the claims drawn to an immunogenic composition.

Under prior art rejections drawn to vaccines, the term vaccine is weighed with the structural limitations of the claim. If the vaccine merely comprises a known composition, the term carries little weight absent evidence of structural difference. The existence of an unobvious structural difference would define over the prior art, applicants will need to clearly point out and claim these structural differences in order to overcome the prior art rejection.

Any one of the Freeman et al. references discloses the use of a B7.2 molecules (SEQ ID NO:2) in a viral vector (see '705, claim 8). The molecule B7.2 (SEQ ID NO:2), also known as CD86, protein sequence at the amino acid level is 71.1% identical to the instantly claimed feline CD86 molecule (this includes conservative mutations). There are numerous stretches of sequence similarity between the claimed CD86 molecule and the B7.2 molecule of the prior art (see attached sequence alignment sheet). The reference discloses the use of viral vectors encoding B7-2 (CD86) for injection into tumor cells for the purpose of expressing the CD86 in a tumor cell (see '705, column 8 lines 12-29 | '310, column 8, lines 4-20 | WO page 41, lines 3-13). Thus the prior art composition anticipates the instant claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 37, 48, 56 and 58 are rejected under 35 U.S.C. 103 (a) as being over Freeman et al. (U.S. Pat. No. 6,723,705; '705), Freeman et al. (U.S. Pat. No. 5,861,310; '310); or Freeman et al. (WO 95/03408; WO) in view of Tripathy D. (Advances in Veterinary Medicine, 1999).

The instant invention is drawn to a viral vector (recombinant virus) that contains at least one foreign nucleic acid inserted into the nucleic acid construct of the viral vector. The vial vector is derived from swinepox virus (claims 41, 54, 76, 77). The insertion site is within a non-essential region. The foreign protein comprises a feline CD86 protein or an immunogenic fragment thereof. The instant specification [paragraph 0056] indicates that the viral vector can

contain DNA sequences that are functional conservative variants, and that can contain additional sequences.

The smallest peptide fragment (epitope) that can elicit an immune response is in an animal is a six amino acid stretch. If the prior art comprises stretches of six amino acids that are the identical or "functional conservative variant" as the instantly claimed CD86 immunogenic fragments then the art meets the limitation of the claims drawn to an immunogenic portion.

Under prior art rejections drawn to vaccines, the term vaccine is weighed with the structural limitations of the claim. If the vaccine merely comprises a known composition, the term carries little weight absent evidence of structural difference. The existence of an unobvious structural difference would define over the prior art, applicants will need to clearly point out and claim these structural differences in order to overcome the prior art rejection.

Freeman et al. teaches the use of a B7.2 molecules (SEQ ID NO:2) in a viral vector (see '705, claim 8). The molecule B7.2 (SEQ ID NO:2), also known as CD86, the protein sequence at the amino acid level including conservative mutations is 71.1% identical to the instantly claimed feline CD86 molecule. There are numerous stretches of sequence similarity between the claimed CD86 molecule and the B7.2 molecule of the prior art (see attached sequence alignment sheet). The reference teaches the use of viral vectors encoding B7-2 (CD86) to introduce into tumor cells for the purpose of expressing the CD86 in a tumor cell (see '705, column 8 lines 12-29 | '310, column 8, lines 4-20 | WO page 41, lines 3-13). The reference teaches using a viral vector to insert the B7-2 (CD86) into a tumor cell, the reference specifically teaches adenoviral vectors or retroviral vectors. The reference does not teach inserting the B7-2 (CD86) into a swine pox viral vector.

Tripathy D. teaches that the use of swinepox vial vectors as a means of introducing foreign genes into an animal for the purpose of vaccinating the animal is well established.

It would have been obvious to insert a CD86 molecule into a viral vector for the purpose of expressing the CD86 molecule in a cell that normally would not express the CD86 as taught by Freeman et al. It would have been obvious to the ordinary artisan to use a swinepox expression system for the purpose of expressing a foreign gene in an animal so that the animal can make an immune response as taught by Tripathy D. The instant invention is obvious over any of Freeman et al. refernces in view of Tripathy D.

Conclusion

No claims allowed.

Papers related this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989). The Group 1600 Official Fax number is: 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Tech Center representative whose telephone number is (571)-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ulrike Winkler, Ph.D. whose telephone number is 571-272-0912. The examiner can normally be reached M-F, 8:30 am - 5 pm. The examiner can also be reached via email [ulrike.winkler@uspto.gov].

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached at 571-272-0902.

ULRIKE WINKLER, PH.D.
PRIMARY EXAMINER